

Safety Data Sheet

According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008 Revision date: 14/12/2015 Date of issue: 14/12/2015

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# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name : Bilirubin Control, Pediatric

Product code : 1331-31, 1332-31

Synonyms : Bilirubin in Human protein matrix

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory Quality Control Material. For professional use only.

**1.2.2.** Uses advised against No additional information available

1.3. Details of the supplier of the safety data sheet

Company

Quantimetrix Corp.

2005 Manhattan Beach Blvd. Redondo Beach, CA 90278

310-536-0006

www.quantimetrix.com

1.4. Emergency telephone number

Emergency number : 310-536-0006

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements : EUH208 - Contains 2-Methyl-4-isothiazolin-3-one(2682-20-4). May produce an

allergic reaction

2.3. Other hazards

No additional information available

# **SECTION 3: Composition/information on ingredients**

#### 3.1. Substance

Not applicable

## 3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Dimethyl sulfoxide	(CAS No) 67-68-5 (EC no) 200-664-3	1	Not classified
2-Methyl-3-isothiazolone	(CAS No) 2682-20-4 (EC no) 220-239-6	0,0152	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aguatic Acute 1, H400

Full text of H-statements: see section 16

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# **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek

medical advice (show the label where possible).

First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area.

First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15

minutes.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : May cause an allergic reaction in sensitive individuals.

Symptoms/injuries after inhalation : Not expected to present a significant inhalation hazard under anticipated

conditions of normal use.

Symptoms/injuries after skin contact : May cause sensitisation of susceptible persons by skin contact.

Symptoms/injuries after eye contact : Direct contact with the eyes is likely irritating.

Symptoms/injuries after ingestion : If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

#### 4.3. Indication of any immediate medical attention and special treatment needed

If medical advice is needed, have product container or label at hand.

# **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray,

fog.

Unsuitable extinguishing media : None known.

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity : Hazardous reactions will not occur under normal conditions.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory

protection.

## **SECTION 6: Accidental release measures**

## 6.1. Personal precautions, protective equipment and emergency procedures

### 6.1.1. For non-emergency personnel

Protective equipment : Use appropriate personal protection equipment (PPE).

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

For containment : Absorb and/or contain spill with inert material, then place in suitable container.

Methods for cleaning up : Clean up spills immediately and dispose of waste safely.

#### 6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection.

# **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Wash

hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when not in

use.

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Incompatible products

: Strong acids. Strong bases. Strong oxidizers.

### 7.3. Specific end use(s)

Laboratory Quality Control Material. For professional use only.

# SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

2-Methyl-4-isothiazolin-3-one (2682-20-4)			
Austria	MAK (mg/m³)	0,05 mg/m³	
Switzerland	VME (mg/m³)	0,2 mg/m³ (inhalable dust)	
Dimethyl sulfoxide (67-68-5)			
Austria	MAK (mg/m³)	160 mg/m³	
Austria	MAK (ppm)	50 ppm	
Austria	OEL chemical category (AT)	Skin notation	
Switzerland	VLE (mg/m³)	320 mg/m³	
Switzerland	VLE (ppm)	100 ppm	
Switzerland	VME (mg/m³)	160 mg/m³	
Switzerland	VME (ppm)	50 ppm	
Switzerland	OEL chemical category (CH)	Skin notation	
Denmark	Grænseværdie (langvarig) (mg/m³)	160 mg/m³	
Denmark	Grænseværdie (langvarig) (ppm)	50 ppm	
Estonia	OEL TWA (mg/m³)	150 mg/m³	
Estonia	OEL TWA (ppm)	50 ppm	
Estonia	OEL STEL (mg/m³)	500 mg/m <sup>3</sup>	
Estonia	OEL STEL (ppm)	150 ppm	
Estonia	OEL chemical category (ET)	Skin notation	
Finland	HTP-arvo (8h) (ppm)	50 ppm	
Finland	OEL chemical category (FI)	Potential for cutaneous absorption	
Lithuania	IPRV (mg/m³)	150 mg/m³	
Lithuania	IPRV (ppm)	50 ppm	
Lithuania	TPRV (mg/m³)	500 mg/m <sup>3</sup>	
Lithuania	TPRV (ppm)	150 ppm	
Lithuania	OEL chemical category (LT)	Skin notation	
Slovenia	OEL TWA (mg/m³)	160 mg/m³	
Slovenia	OEL chemical category (SL)	Potential for cutaneous absorption	
Sweden	nivågränsvärde (NVG) (mg/m³)	150 mg/m³	
Sweden	nivågränsvärde (NVG) (ppm)	50 ppm	
Sweden	kortidsvärde (KTV) (mg/m³)	500 mg/m³	
Sweden	kortidsvärde (KTV) (ppm)	150 ppm	
Sweden	OEL chemical category (SE)	Skin notation	

## 8.2. Exposure controls

**Appropriate Engineering Controls:** Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Gloves. Protective clothing.





Materials for Protective Clothing: Chemically resistant fabrics and materials.

**Hand Protection:** Wear chemically resistant protective gloves. **Eye Protection:** None required under normal conditions of use.

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Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use an approved respirator or self-contained breathing apparatus whenever exposure may exceed

established Occupational Exposure Limits.

Other Information: When using, do not eat, drink or smoke.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : Amber orange
Odour : No data available
Odour threshold : No data available

pH : 8,2

**Evaporation rate** No data available : No data available Melting point Freezing point : No data available **Boiling point** No data available : No data available Flash point Auto-ignition temperature No data available Decomposition temperature : No data available Flammability (solid, gas) : No data available Vapour pressure No data available Relative vapour density at 20 °C : No data available Solubility No data available : No data available Partition coefficient: n-octanol/water Viscosity : No data available **Explosive properties** No data available Oxidising properties : No data available **Explosive limits** : Not applicable

#### 9.2. Other information

No additional information available

# **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

### 10.2. Chemical stability

Product is stable.

### 10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

## 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

## 10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

#### 10.6. Hazardous decomposition products

The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide, carbon dioxide, chloride and hydrocarbons.

## **SECTION 11: Toxicological information**

## 11.1. Information on toxicological effects

Acute toxicity : Not classified

2-Methyl-4-isothiazolin-3-one (2682-20-4)		
ATE CLP (oral)	100,00 mg/kg bodyweight	
ATE CLP (dermal)	300,00 mg/kg bodyweight	
ATE CLP (dust,mist)	0,50 mg/l/4h	
Dimethyl sulfoxide (67-68-5)		
LD50 oral rat	> 20000 mg/kg	

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Dimethyl sulfoxide (67-68-5)		
LD50 dermal rat	≈ 40000 mg/kg	
Skin corrosion/irritation	: Not classified	
Serious eye damage/irritation	: Not classified	
Respiratory or skin sensitisation	: Not classified	
Germ cell mutagenicity	: Not classified	
Carcinogenicity	: Not classified	
Reproductive toxicity	: Not classified	
Specific target organ toxicity (single exposur	e) : Not classified	
Specific target organ toxicity (repeated expo	sure) : Not classified	
Aspiration hazard	: Not classified	

# **SECTION 12: Ecological information**

## 12.1. Toxicity

Dimethyl sulfoxide (67-68-5)	
LC50 fish 1	34 g/l (Exposure time: 96 h - Species: Pimephales promelas)
LC50 fish 2	33 - 37 g/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

## 12.2. Persistence and degradability

Bilirubin Control, Pediatric	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Dimethyl sulfoxide (67-68-5)	
Log Pow	-2,03

## 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

## 12.6. Other adverse effects

Other information : Avoid release to the environment.

## **SECTION 13: Disposal considerations**

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national, and international regulations.

# **SECTION 14: Transport information**

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for trans	sport			
14.2. UN proper s	hipping name			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport ha	azard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing grou	ıρ			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the	Dangerous for the	Dangerous for the	Dangerous for the	Dangerous for the
environment : No	environment : No	environment : No	environment : No	environment : No
	Marine pollutant : No			

### 14.6. Special precautions for user

No additional information available

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## 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

# **SECTION 15: Regulatory information**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

#### 2-Methyl-3-isothiazolone (2682-20-4)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

## Dimethyl sulfoxide (67-68-5)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

#### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## **SECTION 16: Other information**

Revision date : 14/12/2015

Data sources : According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Sensitisation — Skin, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life

EU GHS SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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